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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,845	01/13/2000	DAVID A. ESTELL	GC382-US	5579

5100 7590 07/16/2003

GENENCOR INTERNATIONAL, INC.  
ATTENTION: LEGAL DEPARTMENT  
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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/462,845	ESTELL, DAVID A.
	Examiner Yong D Pak	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 May 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-7,9-11,16,17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1,3-7,9-11,16,17 and 19 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

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### **DETAILED ACTION**

The response filed on May 8, 2003 has been entered. This application is a 371 of PCT/FI99/00410.

Claims 1, 3-7, 9-11, 16-17 and 19 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

#### ***Response to Arguments***

Applicant's arguments filed on May 8, 2003 have been fully considered but they are not persuasive.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 9-11, 16-17 and 19 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the specification describes how to produce mutated SP1 and that both the structure and function of mutant SP1s are described. The examiner disagrees. As previously stated, the specification does not contain any disclosure of the structure and function of all mutant SP1 genes resulting from mutation or deletion of part of the SP1 gene. Contrary to applicants arguments, a "representative number" of species is not described in the specification. Applicants argue that the specification describes how to make mutants of SP1 having an inactivated SP1 activity. Pages 5-13 refer to a general method of introducing mutations or deletions to SP1 by site-specific mutagenesis. However, the genus of the mutant SP1 is so broad that many structurally and functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences. The specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of encoding a polypeptide with an inactivated SP1 proteolytic activity and fails to provide any structure: function correlation present in all members of the claimed genus.

Claims 1, 3-7, 9-11, 16-17 and 19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for gram-positive microorganism having any mutation or deletion of part of all of SEQ ID NO:1 resulting in a mutant gene that inactivates SP1 proteolytic activity. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the specification is enabling because the specification teaches that residues in the catalytic domain may be deleted or mutated to inactivate the activity of the polypeptide. Pages 5-13 refer to a general method of introducing mutations or deletions to SP1 by site-specific mutagenesis. However, the claims encompass extremely large number of constructs that are drawn beyond mutant having mutations or deletions at the catalytic triad, such as partial DNA sequences. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

Therefore, one of ordinary skill would require guidance in order to make gram-positive microorganisms having a mutation or deletion of part of all of the gene encoding SP1 (SEQ ID NO:1), wherein resulting mutation or deletion results in the inactivation of the SP1 proteolytic activity in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

No claims are allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

July 10, 2003



PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600